

RESPONSE

Claims 2, 5-9, 14, 15 and 17 are pending in the application. Claims 8 and 9 are withdrawn from consideration by the Examiner. Claims 2, 5-7, 14, 15 and 17 are rejected.

Claim 2 is amended herein. Claims 8 and 9 are cancelled herein. Following entry of the enclosed amendment, claims 2, 5-7, 14, 15 and 17 are pending.

Claim Rejections – 35 USC § 112

(1) Claims 2, 14-15 and 17 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While being enabled for method of increasing glucose utilization, treating diabetes or obesity and/or impaired glucose tolerance with the administration of the specific compound of the formula III, does not reasonable provide enablement for treating atheosclerosis, hypertension, dyslipidemia, coronary heart disease, gallbladder disease, osteoarthritis, endometrial cancer, breast cancer, prostate cancer and colon cancer with all compounds encompassed by the instant invention.

While not acquiescing to the merits of the Examiner's rejection, but to expedite prosecution, Applicants have amended claim 2 to include only those diseases, conditions and disorders noted by the Examiner as being enabled. For this reason, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2, 14, 15 and 17 under 35 USC § 112, first paragraph.

(2) Claims 2, 14, 15 and 17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent

protection desired. Specifically, claim number 2 recites the broad recitation “diabetes”, and the claim also recites “type 2 diabetes”, which is the narrower statement of the range limitation.

Applicants respectfully disagree with the Examiner. Applicants direct the Examiner’s attention to MPEP 2173.05(h), wherein it is stated that “the Markush group, ‘selected from the group consisting of amino, halogen, nitro, chloro and alkyl’ should be acceptable even though ‘halogen’ is generic to ‘chloro’.” This is similar to the instant situation, wherein diabetes is generic to the term type 2 diabetes. In addition, “The following phrases were each held to be acceptable and not in violation of 35 USC § 112, second paragraph in *In re Gauber*, ... ‘iron, steel or any other magnetic material’.” Again, this holding is directly on point with the instant situation.

However, in the spirit of compact prosecution, while not acquiescing to the merits of the invention, Applicants have removed “type 2 diabetes” from claim 2, with the understanding that this term is included in the broader term “diabetes”.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2, 14, 15 and 17 under 35 USC § 112, second paragraph.

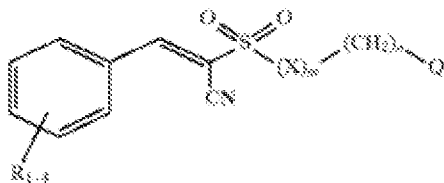
Claim Rejections – 35 USC § 102

(3) Claims 2, 14 and 15 are rejected under 35 USC § 102(b) as being anticipated by Tang et al. (US 5,891,917).

Tang discloses the use of small organic molecules to prevent and treat cell proliferative disorders or cell differentiation disorders associated with particular tyrosine kinases by inhibiting one or more abnormal tyrosine kinase activities. See Tang, Field of the Invention.

Tang differs from the present invention in two aspects. First, the compounds of Tang are structurally different from those of the present invention. Second, the instant invention is drawn to methods of treating obesity, diabetes, and impaired glucose tolerance, whereas Tang is drawn to the treatment of cell proliferative and differentiation disorders.

Tang describes compounds having the formula



These acrylonitrile compounds may include a para-hydroxy substituent on the benzene ring. All of the compounds of Tang, however, are acrylonitriles, whereas none of the compounds of the present invention may be acrylonitriles. Therefore, because the compounds of Tang differ from the compounds of the present invention, Tang does not anticipate the present invention.

Moreover, Tang is directed to the prevention and treatment of cell proliferative disorders or cell differentiation disorders. The present invention is drawn to methods of treating obesity, diabetes, and impaired glucose tolerance. While Tang does generically discuss diabetes (“Uncontrolled vasculogenesis and/or angiogenesis has been associated with diseases, such as diabetes....” Tang at column 10, lines 24-26) (“The invention is further based on the observation that diseases such as diabetes mellitus ... and arthritis, as well as malignant tumor growth may result from uncontrolled angiogenesis.” Tang at column 10, lines 34-39), Tang does not teach or fairly suggest that the compounds of Tang may be used to treat diabetes. After discussing this background information, Tang discloses that the present invention related to compounds capable of regulating and/or modulating tyrosine signal transduction and more particularly KDR/FLK-1 receptor signal transduction in order to “inhibit or promote angiogenesis and/or vasculogenesis.” Tang at column 10, lines 54-55. Thus, it would appear that these compounds may inhibit or promote angiogenesis and/or vasculogenesis. From the previous discussion in Tang, it would appear that uncontrolled angiogenesis may result in diabetes mellitus. Therefore, there appears to be no direction in Tang whether the compounds disclosed therein may help diabetes, or whether they may even cause diabetes.

For the above plurality of reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2, 14 and 15 as being anticipated by Tang.

Claim Rejections – 35 USC § 103

(4) Claims 2, 5-7, 14, 15 and 17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bachynsky (US 4,673,691, issue date June 16, 1987) in view of Batt et al. (US 5,593,994, issue date January 14, 1997) and Rink et al. (US 5,739,106, issue date April 14, 1998) as applied to claims 4-7.

Applicants respectfully submit that the Examiner has engaged flawed scientific and legal reasoning to arrive at the present invention.

It is noted, and Applicants agree, that Bachynsky teaches 2,4-dinitrophenol (DNP) which is a known agent for the treatment of obesity. As further correctly noted by the Examiner, the compound differs from those of the present invention in that the Bachynsky compound has a nitro group at the 4-position of the benzene ring and the present invention does not require such a substituent.

In the sentence bridging pages 10 and 11 of the Office Action, the Examiner states that “the base structure of the prior art compound 2,4-dinitrophenol is the same as the base structure of 4-hydroxy-3-nitroacetophenone of the instant invention.” Applicants disagree with this broad generalization. DNP and 4-hydroxy-3-nitroacetophenone are two distinct and different compounds. Applicants respectfully submit that no person of ordinary skill in the pharmaceutical and/or organic chemical arts would consider a nitro group the same as an aceto group.

The Examiner appears to rely on Batt, which discloses compounds wherein a benzene ring may be substituted by either a nitro group or an aceto group. It would appear that the Examiner is leaping to the conclusion that, because two radicals are presented in a Markush group as possible substituents for one compound, that the interchange of these two radicals in a completely different compound would be obvious. Applicants wholeheartedly disagree.

By taking the Examiner’s logic to the next step, it would appear that the substitution of a hydrogen atom on a benzene ring by a hydroxyl, nitro or aceto would be obvious, regardless of the rest of the compound. Going even a step further, the R³ radical of Batt (for which the Examiner relies upon for the conclusion that a nitro group renders obvious an aceto group on any benzene ring) may also be F, Br, Cl, alkyl, amino, and the like (see Batt at column 47, lines 16-

20). Under the Examiner's logic, it would be obvious to replace a nitro group on any benzene ring on any chemical compound with any of the substituents listed for R³. Such a conclusion, however, is not obtainable under 35 USC § 103.

Taking a step back, looking to the Office Action, it is stated that "One having ordinary skill in the art would have been motivated to substitute a nitro group of the prior art compound with an aceto group with the expectation that the substitution would not significantly alter the analogous properties of the compound due to close structural similarity of the compounds. Applicants disagree with this statement, inasmuch as it is understood. In trying to understand this statement, it would appear that the analogous properties to which the Examiner mentions refers to the fact that Bachynsky and the present invention both describe compounds that may be useful for the treatment of obesity.

The Examiner states that the substitution (of a nitro group with an aceto group) would not significantly alter the analogous properties of the compound "due to the close structural similarity of the compounds." Applicants are confused as to which compounds have close structural similarity. The compounds of the present invention and those of Bachynsky may be similar, but, as stated above, are different and distinct. Even so, there would be no motivation in either Bachynsky or the present invention to substitute the nitro group of Bachynsky with an aceto group. The motivation (albeit, as described above, logically and scientifically flawed) appears to come from Batt. However, the compounds of Batt are very structurally dissimilar from those of the present invention and/or Bachynsky. Therefore, Applicants see no reason why a person of ordinary skill in the art would replace the nitro group on 2,4-dinitrophenol with an aceto group, particularly at the 4-position, to arrive at the compounds useful in the methods of the present invention.

For the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claim number 2, 5-7, 14, 15 and 17 under 35 USC § 103(a).

(5) Claims 5-7 are rejected under 35 USC § 103(a) as being unpatentable over Tang et al. (US 5,891,917) in view of Tang et al. (US 6,514,981).

As noted above, Tang '917 does not teach or fairly suggest the compounds useful in the methods of the instant invention. Tang '981 does not overcome this deficiency in Tang '917.

Therefore, the combination of Tang '917 with Tang '981 does not anticipate or render obvious the present invention.

Applicants respectfully request reconsideration and withdrawal of the rejection of claims number 5-7 under 35 USC § 103(a).

The examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application. Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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